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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,424	12/22/2000	Ram Pratap	K&S-0100-US	8031

7590 11/12/2003

Supervisor, Patent Prosecution Services
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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/742,424

Applicant(s)

PRATAP ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (2 months) and the Amendment, both filed 09/08/03 is acknowledged.

The 35 U.S.C. 102(e) anticipation rejections have been withdrawn.

Claims 1-12 are pending. Claim 1 has been amended. Claims 1-12 stand rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed *et al.* (US Pat. No. 6,436,991; hereafter '991).

Majeed *et al.* teaches compositions and methods comprising administration of an ethyl acetate extract of gum guggul (i.e., gugulipid) to treat memory disorders such as Alzheimer's Disease (AD) (see Abstract, col. 2, line 1-6; col. 3, line 31-53; col. 4, line 24-48; examples and claims). Majeed teach a dosage level of 0.01-300 μ M or 0.01 mg/kg to 5 mg/kg. Instant claim 9 requires that a dosage of gugulipid equivalent to 40 mg/kg/day for 7 days is administered but does not state what the actual amount is.

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Since both the instant claims and '991 are directed towards treating memory dysfunctions resulting from Alzheimer's, the dose of '991 is also considered to be equivalent to this dose.

Majeed et al. does not teach the instant steps reciting the process by which the guggulipid is obtained, however, in the absence of data, these limitations are not afforded patentable weight in that the invention lies in the method of treatment with the compound.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US Pat. No. 6,436,991; hereafter '991) in view of Reilly, Jr. (in Remington's, 1995).

Majeed et al. teach compositions and methods comprising administration of an ethyl acetate extract of gum guggul (i.e., guggulipid) to treat memory disorders, such as Alzheimer's Disease (AD) (see Abstract, col. 2, line 1-6; col. 3, line 31-53; col. 4, line 24-48; examples and claims). While '991 teaches the inclusion of pharmaceutically acceptable carriers, diluents and fillers, it does not name specific examples of these.

Reilly is relied upon for the teaching that the instant claimed additives are known pharmaceutical carriers or fillers.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer the compounds of '991 with an ingredient selected from the group of instant claim 4.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeed et al. (US Pat. No. 6,436,991; hereafter '991) in combination with Standaert and Young (in Goodman and Gilman's, 1996).

Majeed et al. ('991) is relied upon for all that it discloses as stated previously. '991 does not teach that Alzheimer's Disease (AD) is an "anticholinergic induced amnesia" as recited in instant claim 8. Standaert and Young is relied upon to show that this is inherent in (AD). Accordingly, '991 also obviates claim 8.

Response to Arguments

Applicant's arguments filed 09/08/03 have been fully considered but they are not persuasive.

Firstly, the applicant argued regarding the 35 U.S.C. 102(e) rejections. Applicant's arguments with respect to claims 1-3 and 5-12 have been considered but are moot in view of the new ground(s) of rejection.

Secondly, the applicant argued, "The claims are drawn to a method requiring utilization of a specific extract product made by a particular process. Majeed et al. fails to teach what portion of the plant is extracted, or the particular extraction steps accessed. Neither Majeed et al, nor the secondary reference teach or suggest guggulipid according to the claimed invention. Majeed is limited to disclosing Alzheimer's disease, and no other forms of memory dysfunction. In addition, Majeed et al. is directed to the disclosure of ferulate compounds, not guggulipid. For the treatment

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of memory dysfunction, Majeed et al. is directed to the use of these ferulate compounds and does not disclose the use of guggulipid for treating such an indication.”

These arguments have been fully considered, but were not found to be persuasive. Majeed et al., as delineated above, teaches compositions and methods comprising administration of an ethyl acetate extract of gum guggul (i.e., guggulipid) to treat memory disorders such as Alzheimer’s Disease (AD). The applicant’s argument that ‘Majeed et al. fails to teach what portion of the plant is extracted, or the particular extraction steps accessed’ is not persuasive since there are no advantageous properties shown or described in the particular method steps used to obtain the guggulipid ingredient. The burden is on the applicant to show the importance of the instant method steps. The prior art teaches a similar composition and method for treating memory disorders of Alzheimer’s disease, through the administration of an ethyl acetate extract of gum guggul or guggulipid. As such, there are no significant distinctions observed between the instant invention and the prior art. Hence, the instant invention is rendered obvious and unpatentable over the prior art of record.

Conclusion

Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

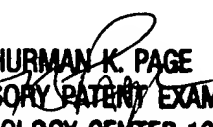
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

November 11, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600